



## **ASX RELEASE**

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### **FDA PROVIDES GUIDANCE ON THE CLINICAL DEVELOPMENT OF CANTRIXIL**

**SYDNEY (October 1, 2014)** – Novogen Ltd (ASX: NRT; NASDAQ: NVGN) and its subsidiary company, CanTx Inc, have received guidance from the US Food and Drug Administration (FDA) on the process underway to bring the experimental drug product, Cantrixil, into the clinic in the US for the treatment of late-stage ovarian cancer.

The guidance relates to the drug manufacturing scale-up process, the pre-clinical animal testing program, and the general design of the Phase 1 study in achieving Investigational New Drug (IND) status for a first-in-man study in the US. This is advice only, designed to ensure that companies are following generally approved processes. It does not guarantee that an IND will be granted eventually.

Dr Graham Kelly, Novogen CEO and Executive Chairman, said today, “We are very familiar with the IND application process and this guidance would not normally be of any great significance, except for the fact that Cantrixil is a first-in-class product, being developed as an intra-cavity anti-cancer product. What this means is that it has been designed to be delivered directly into cavities such as the peritoneal cavity (abdomen) and the pleural cavity (thorax). That first-in-class status had the potential to have raised issues by the regulator. Fortunately, no such issues were flagged.”

The Phase 1 clinical trial will be conducted in women with late stage ovarian cancer. Cantrixil will be injected directly into the peritoneal cavity, which is where ovarian cancer spreads once it leaves the ovary. The drug candidate in Cantrixil, TRX-E-002-1, has been selected for its potent ability to kill ovarian cancer stem cells, the cells believed responsible for spreading the cancer throughout the abdomen. The rationale is that by injecting Cantrixil directly into the peritoneal cavity, the cancer stem cells and their daughter cells are exposed to much higher levels of the drug candidate than would be achieved by intravenous injection.

“While this particular IND process is directed at the use of Cantrixil to treat late-stage ovarian cancer, the product has been designed to treat any form of disseminated cancer within the abdomen. This condition is known as peritoneal carcinomatosis and is a late-stage condition associated mostly with cancers that arise in the abdominal cavity, such as colo-rectal cancer, ovarian cancer and primary peritoneal cancer. No standard of care exists currently

for these conditions, and as far as we know, Cantrixil is the first product to be developed for these conditions, despite their prevalence”, Dr Kelly added.

### **About Novogen Limited**

Novogen is a public, Australian drug-development company whose shares trade on both the Australian Securities Exchange ('NRT') and NASDAQ ('NVGN'). The Novogen Group includes a New Haven CT – based joint venture company, CanTx Inc, with Yale University.

Novogen has two main drug technology platforms: super-benzopyrans (SBPs) and anti-tropomyosins (ATMs). SBP compounds have been created to kill the full range of cells within a tumor, but particularly the cancer stem cells. The ATM compounds target the microfilament component of the cancer cell and when used in conjunction with standard anti-microtubular drugs, result in comprehensive and fatal destruction of the cancer cell's cytoskeleton. Ovarian cancer, colorectal cancer, malignant ascites, prostate cancer, neural cancers (glioblastoma, neuroblastoma in children) and melanoma are the key clinical indications being pursued, with the ultimate objective of employing both technologies as a unified approach to first-line therapy.

### **About CanTx**

CanTx Inc is a private biotechnology company based in New Haven, Connecticut, and established as a joint venture between Novogen and Yale University. CanTx is dedicated to the development of anti-cancer drugs for the treatment of ovarian cancer.

Further information is available on our websites [www.novogen.com](http://www.novogen.com) and [www.can-tx.com](http://www.can-tx.com)

For more information please contact:

#### **Corporate Contact**

Executive Chairman & CEO  
Novogen Group  
[Graham.Kelly@novogen.com](mailto:Graham.Kelly@novogen.com)  
+61 (0) 2 9472 4100

#### **Media Enquiries**

Operations Manager  
[Cristyn.Humphreys@novogen.com](mailto:Cristyn.Humphreys@novogen.com)  
+61 (0) 2 9472 4111

#### **Investors Enquiries**

Executive Chairman & CEO  
Novogen Group  
[Graham.Kelly@novogen.com](mailto:Graham.Kelly@novogen.com)  
+61 (0) 2 9472 4100